UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,052	04/05/1999	SHUJI SAITOH	981167	1182

23850 7590 11/13/2003

ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP
1725 K STREET, NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	30

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/147,052	Applicant(s) SAITOH ET AL.	
	Examin r Ja-Na Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears n the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-46* is/are pending in the application.

4a) Of the above claim(s) *31,34-38,45 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-30,32,33 and 39-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The amendment filed April 10, 2003 has been entered. Claims 20 and 25-26 have been amended. Claims 27-46 have been newly added. Newly submitted claims 31, 34-38 and 45-46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The inventions are related as different products. The products are distinct as claimed because they have different structures and different uses. The DNA coding for a fusion protein and associated components have a different structure and use when compared to the other originally presented claims. This group has a different function, effect and is capable of use without the other. For instance, an isolated DNA can encode an antigenic polypeptide yet the other group cannot. Each group has a different structure, produces different effects and has a different function from the other group. Therefore, the products of the inventions are distinct as claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31 and 34-38, 45-46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Therefore claims 20-30, 32-33 and 39-44 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The enablement rejection of claim 26 under 35 U.S.C. 112, first paragraph;

b) The written description rejection of claims 25-26 under 35 U.S.C. 112, first paragraph; and

c) The rejection of claims 25-26 under 35 U.S.C. 112, second paragraph.

Response to Arguments

3. Applicant's arguments filed April 10, 2003 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The rejection of claims 20-24, 29-30 and 41-42 under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200) is maintained.

Applicants argue that the lack of in vivo results in Sajto are the reason why a skilled in the art would not use the Sajto disclosure to prepare a hybrid fusion protein or recombinant virus with a view at preparing a live vaccine. However it is the examiner's position that the MPEP section 2123 teaches that patents are relevant as prior art for all

they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). Therefore applicant's argument is not persuasive especially when considering the prior teaches the use of the same antigenic *Mycoplasma gallisepticum* protein and a signal polypeptide of the outer membrane protein comprised as a fusion protein and recombinant Avipox virus.

The functional limitation of the instant claims drawn to in vivo activity does not result in a structural difference. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case the prior art is capable of performing the intended function. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to

some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). As such applicants arguments drawn to in vivo activity is not found persuasive.

Applicant argues that the references teach away from the claimed invention because the prior art comprises membrane-anchoring sequences. However, it is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132. Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims.

Moreover, the M.P.E.P. section 2111.03 states that the transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). It is noted that applicants' argument that the subunit vaccine is more effective that the Cutter vaccine is therefore, not persuasive, since the instant claims do not become patentable simply because they have been described as somewhat inferior to some other product for the same use. Therefore applicants' arguments about the membrane anchoring sequence are unpersuasive, since the claims comprises open language.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill would have been required to use the signal polypeptide derived Herpes outer membrane protein from Yoshida et al., (Virology 1994 Vol. 200) with the fusion protein comprising an outer membrane protein that infects birds and vaccine of Saito et al., (WO 94/23019) because Yoshida et al., teach that the FPV recombinant express the gB-1 gene which can elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV; the FPV recombinant is a good candidate for an MDV vaccine; and that gB is an important target for the host immune response thus providing motivation for inclusion. One would have a reasonable expectation of success to use the fused polypeptide comprising a signal polypeptide and exchange the signal polypeptide of Saito et al., for the signal polypeptide of Yoshida et al., because of the many beneficial effects Yoshida et al., teach.

The use of functionally equivalent technique or component would have been desirable to those of ordinary skill in the art based on the prior use and well-known advantages of such compositions and vaccines based on the ease and availability of the components. Moreover, no more than routine skill is required to make such a change as a mere alternative and functionally equivalent polypeptide since only the expected results are taught. The use of alternative signal polypeptides would have been desirable to those of ordinary skill in the art based on the fact that gB-1 gene elicits neutralizing antibody; fully protects chickens against virulent strains of MDV and it

is a good candidate for an MDV vaccine. Therefore, the cited prior art clearly teaches these aspects of the instant claims, thus the rejection is maintained.

Therefore applicants' arguments are not persuasive and the rejection is maintained.

Even though, antigenicity testing is not recited in the claims, Saito et al., teach the expression with a recombinant virus of a polypeptide modified to such an extent as to exhibit antigenicity equivalent to that of any of the above polypeptides. Thus, Saito et al., teach antigenicity. Furthermore, the claims are not drawn to the fusion proteins with the ability to prevent infection, therefore this argument is not persuasive.

5. The rejection of claims 25-26 and 32-33 under 35 U.S.C. 103(a) as being unpatentable over Saito et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200) and further in view of Yangida et al., is maintained for the reasons stated above and in the prior office actions.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Sajto et al., (WO 94/23019) and Yoshida et al., (Virology 1994 Vol. 200) have been discussed above. Yangida et al., teach recombinant Avipox virus having all or part of cDNA for Newcastle disease virus derived fused proteins. Thus, it would have been obvious at the time of applicants invention to use the recombinant

Avipox virus with exogenous DNA as taught by Yangida et al, with the fusion polypeptide of Saito et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200) because Yangida et al., teach that recombinant Avipox virus genes are effective as vaccine and can prevent infections of Avipox virus.

New Grounds For Rejection
Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 25-26, 32-33, 40-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are drawn to a recombinant Avipox virus or recombinant live vaccine with the ability to secrete the antigenic protein extracellularly, outside the cell, at the surface of the cell and does not include a membrane anchor sequence.

Neither the specification nor originally presented claims provides support for a recombinant Avipox virus or recombinant live vaccine with the ability to secrete the antigenic protein extracellularly, outside the cell, at the surface of the cell and does not include a membrane anchor sequence.

Applicant did not point to support in the specification for a recombinant Avipox virus or recombinant live vaccine with the ability to secrete the antigenic protein extracellularly, outside the cell, at the surface of the cell and does not include a membrane anchor sequence. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of a recombinant Avipox virus or recombinant live vaccine with the ability to secrete the antigenic protein extracellularly, outside the cell, at the surface of the cell and does not include a membrane anchor sequence. Pages 8 and 10 of the instant specification and previous claims fail to teach a recombinant Avipox virus or recombinant live vaccine with the ability to secrete the antigenic protein extracellularly, outside the cell, at the surface of the cell and does not include a membrane anchor sequence. Thus, there appears to be no teaching of a recombinant Avipox virus or recombinant live vaccine with the ability to secrete the antigenic protein extracellularly, outside the cell, at the surface of the cell and does not include a membrane anchor sequence. Moreover it appears that the entire specification appears to fail to recite support for the newly recited recombinant Avipox virus or recombinant live vaccine with the ability to secrete the antigenic protein extracellularly, outside the cell, at the surface of the cell and does not include a membrane anchor sequence. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of a recombinant Avipox virus or recombinant live vaccine with the ability to secrete the antigenic protein extracellularly, outside the cell, at the surface of the cell and does not

include a membrane anchor sequence as recited by the newly added amendments. Therefore, the new claims incorporate new matter and are accordingly rejected.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found above in the Office action.

8. Claims 27, 29 and 41-42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al., (WO 94/23019) and Yoshida et al., (Virology 1994 Vol. 200) and further in view of Nazerian et al. (EP 520,753). Saito et al., (WO 94/23019) and Yoshida et al., (Virology 1994 Vol. 200) have been discussed above and in previous office actions, however neither teach a signal polypeptide with amino acids 1-672 of SEQ ID NO:4.

Nazerian et al., teach Marek's disease as a highly contagious neoplastic disease of domestic chickens and is caused by a highly cell-associated oncogenic herpesvirus known as Marek disease virus (MDV) (page 2). Recombinant DNA technology has allowed the construction of recombinant vaccines that contain only those desired viral genes or gene products that induce immunity without exposing the animal to genes that may induce pathological disorders (page 2). Pox viruses, including avipox virus provide excellent models for such vaccines since these viruses have large DNA molecule with numerous nonessential regions that allow the insertion of several immunogenic genes into the same virus for the purpose of creating multivalent vaccines (page 2). MDV

homologus of the Herpes simplex virus gene code for glycoproteins that have been recently cloned (page 2). It was an object of the invention to provide effective and safe vaccines against MDV that expose and immunize chickens to the immunogenic products of the vaccine (page 2). Example 2 teaches cloning of the gene to produce recombinant viruses used for immunizing chickens (page 5-6). Thereby teaching a signal polypeptide encompassing an identical sequence to both 1-63 of SEQ ID NO:1 and 1-672 of SEQ ID NO:4 as recited by the instant claims. Moreover, Nazerian et al, teach the ability of the recombinant fusion polypeptides comprised within the virus and vaccine as having the ability to induce humoral immunity in chickens (page 7-8) See also Table 1.

Therefore it would have been prima facie obvious at the time of applicants invention to incorporate well known sequences, usual in the same field of art, for the same immunity creating purpose as taught by Nazerian et al. No more than routine skill would have been required to use the signal polypeptide derived Herpes outer membrane protein from Yoshida et al., (Virology 1994 Vol. 200) and the fusion protein comprising an outer membrane protein that infects birds and vaccine of Saito et al., (WO 94/23019) because the prior art teaches that signal polypeptides are useful in directing polypeptides. One of ordinary skill in the art would have clearly been motivated to use the fused polypeptide comprising a signal polypeptide and exchange the signal polypeptide for that of Nazerian et al., because of the many beneficial effects the prior art teaches. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent polypeptide since only

the expected results are taught. The use of alternative signal polypeptides would have been desirable to those of ordinary skill in the art based on the fact that gB-1 gene elicits neutralizing antibody; fully protects chickens against virulent strains of MDV and it is a good candidate for an MDV vaccine.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

November 3, 2003

MARK NAVARRO
PRIMARY EXAMINER